Focus Report

New Chemicals Program

PMN Number: **P-13-0816**

Focus Date:	08/28/2013 11:00:00 PM	Report Status:	In Progress
Consolidated Set:	P-13-0816; P-13-0817; P-13-0818; P-13-0819; P-13-0820; P-13-0821		
Focus Chair:	Brian Lee	Contractor:	Olga Svetlitskaya

I. Notice Information

Submitter: [redacted]

CAS Number: [redacted]

Chemical Name: [redacted]

Use: inhibitor [redacted]

Other Uses:

PV-Max:

Manufacture: X

Import:

II. SAT Results

(1) **Health Rating:** 1-2 **Eco Rating:** 3 **Comments:** ;

Occupational: 0-1 **Non-Occupational:** NR **Environmental:** NR

(1) **PBT:** 1 1 1 **Comments:**

Awaiting Human Health Entry

Awaiting Human Health Entry

Awaiting Human Health Entry

III. OTHER FACTORS

Categories:

Health Chemical Category:

Ecotox SAR and TSCA New Chemical Category: Aliphatic Amines; Aliphatic Amines

Related Cases/Regulatory History:

Health related Cases:

Ecotox Related Cases:

Regulatory History: [redacted]

CRSS P2Rec: P2Rec-P2 Recognition; SF-Sustainable Futures; XL-Excellence and Leadership; YX-Exposure-Based 5(e)

MSDS/Label Information:

MSDS: Yes Label: No

General Equipment: General ventilation is recommended. Use local exhaust ventilation if necessary to control airborne mist and vapor. // Wear safety glasses with side-shields. // When handling this product, the use of chemical gauntlets is recommended. The choice of work glove depends on work conditions and what chemicals are handled. // Wear chemical resistant apron, chemical splash goggles, impervious gloves and boots. A full slicker suit is recommended if gross exposure is possible.

Respirator: Where concentrations in air may exceed the limits given in this section, the use of air supplied

	breathing apparatus is recommended. In event of emergency or planned entry into unknown concentrations a positive pressure, full-facepiece SCBA should be used.
Health Effects:	Eyes: May cause irritation with prolonged contact. // Skin: May cause irritation with prolonged contact. Toxic in contact with skin. Methanol may be absorbed through the skin and cause central nervous system effects which may result in permanent visual changes including blindness. Skin contact may aggravate an existing dermatitis condition. // Ingestion: Not a likely route of exposure. May cause nausea and vomiting. Can cause central nervous system depression. Toxic if swallowed. Sublethal doses may cause central nervous system effects and may result in permanent visual changes including blindness. // Inhalation: Toxic by inhalation.
TLV/PEL (PMN or raw material):	- Methanol (CASRN 67-56-1) - 60 wt% - TWA - ACGIH - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - ACGIH - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - OSHA Z1 - Methanol (CASRN 67-56-1) - 60 wt% - TWA - OSHA Z1

Exposure Based Information:

Exposure Based Review: [redacted]	Exposure Based Review (Health): [redacted]
Exposure Based Review (Eco): [redacted]	Exposure Based (Occupational): [redacted]
Exposure Based Review (Non Occupatuional):	Exposure Based (Environmental):

IV. Summary of SAT Assessment

Fate:

Fate Summary:

P-13-0816-21 [redacted]
FATE: Estimations for example [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
FATE: Estimations for typical [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 1.77 (E)
log Fish BAF = 1.51 (E)
PMN Substance: [redacted]
[redacted]
POTW removal (%) = 90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = v.strong
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary: Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for surfactant effects on the lung; irritation to eye, mucous membranes and lung based on surfactant properties of the compound.

Ecotox:

Ecotox Values:

Fish 96-h LC50:	0.504 or *(P)
Daphnid 48-h LC50:	5.3(P)
Green algal 96-h EC50:	0.034(P)
Fish Chronic Value:	0.009(P)
Daphnid ChV:	0.010(P)
Algal ChV:	0.015(P)

Ecotox values comments: Predictions are based on SARs for aliphatic amines with a molecular weight adjustment; SAR chemical class = aliphatic amines; [redacted]; effective concentrations based on 100% active ingredients and mean measured concentrations; DWhardness <150.0 mg/L as CaCO3; and DWTOC <2.0 mg/L;

Ecotox Factors:

Assessment Factor:	10
Concern Concentration: - Acute Value	
Concern Concentration: - Chronic Value	1

V. Summary of Exposures/Releases

Engineering Summary: P-13-0816

Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-13-0816

Exposures/Releases	Release		
Scenario	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]			
[redacted]			
[redacted]			
[redacted]	[redacted]		
Workers			
Exposure Type			

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: PMN Consent Order Decision Date: 08/28/2013
Type of Decision:

Rationale: P-13-0816 will be regulated under the TSCA 5(e) category (aliphatic amines) under the exposure-based authority for ecotoxicity and fate concerns. [redacted] Human health hazard concerns were low-moderate for inhalation exposures. Potential risks to workers were mitigated by negligible vapor exposures. Ecotoxicity hazard concerns were high based on SAR predictions for aliphatic amines. Potential risks to the environment were low due to no exceedances of the COC during the release period. The required ecotoxicity will be the general test strategy in the NCP Chemical Categories document and will be tiered based on the outcome of the fate testing. The required fate testing will be water solubility, Koc and log kow, all in salt water. The submitter may be asked for effluent measurements from [redacted]. As of the date these FOCUS notes were finalized EAB has not confirmed the fate testing. The P2REC will not be forwarded based on the high ecotoxicity.

COC: Chronic- 1 ppb, Acute- 9 ppb

Summary of Exposures and Releases

Manu
[redacted]
Dermal: Not required, per SAT

Releases via Incineration: [redacted]

Proc
[redacted]
Dermal: Not required, per SAT

Releases via Incineration: [redacted]

Use
[redacted]
Dermal: Not required, per SAT

Releases to Water: [redacted]

P2 Rec Comments:

Testing:

Prefocus Recommended:

Eco: Chronic Base-Set Tests

Species	EPA Test Guidance	Other parameters
Fish Early Life-Stage	OCSPP 850.1400	Flow-through method, mean measured concentrations, certificate of analysis
Chronic Daphnia	OCSPP 850.1300	Flow-through method, mean measured concentrations, certificate of analysis
Algae	OCSPP 850.4500	Static, mean measured concentrations, protocol review, certificate of analysis

Final Recommended:

Health:

Eco:

Fate:

Other:

SAT Report

PMN Number: **P-13-0816**
SAT Date: **8/23/2013**
Print Date: **6/8/2015**

Related cases: [redacted]

Health related cases:
Ecotox related cases:

Concern levels:

Type of Concern:	**Health**	**Eco**	**Comments**
Level of Concern:	1-2	3	

Persistence	**Bioaccum**	**Toxicity**	**Comments**
1	1	1	
		Awaiting Human Health Entry	
		Awaiting Human Health Entry	
		Awaiting Human Health Entry	

Exposure Based Review:

Health: No
Ecotox: Yes **Exposure based testing (eco):** Chronic Base-Set Tests

Species	EPA Test Guidance	Other parameters
Fish Early Life-Stage	OCSPP 850.1400	Flow-through method, mean measured concentrations, certificate of analysis
Chronic Daphnia	OCSPP 850.1300	Flow-through method, mean measured concentrations, certificate of analysis
Algae	OCSPP 850.4500	Static, mean measured concentrations, protocol review, certificate of analysis

Routes of exposure:

Health: Inhalation
Ecotox: All releases to water
Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: P-13-0816-21 [redacted]
FATE: Estimations for example [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
FATE: Estimations for typical [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 1.77 (E)
log Fish BAF = 1.51 (E)
PMN Substance: [redacted]
[redacted]
POTW removal (%) = 90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = v.strong
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary: Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for surfactant effects on the lung; irritation to eye, mucous membranes and lung based on surfactant properties of the compound.

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	**96-h**	**LC50**	0.504 or *		
daphnid	**48-h**	**LC50**	5.3		
green algal	**96-h**	**EC50**	0.034		
fish	**_**	**chronic value**	0.009		
daphnid	**_**	**chronic value**	0.010		
algal	**_**	**chronic value**	0.015		

Sewage Sludge	**3-h**	**EC50**	**_**		
Sewage Sludge	**_**	**Chronic Value**	**_**		

Ecotox Values Comments: Predictions are based on SARs for aliphatic amines with a molecular weight adjustment; SAR chemical class = aliphatic amines; [redacted] effective concentrations based on 100% active ingredients and mean measured concentrations; DWhardness <150.0 mg/L as CaCO3; and DWTOC <2.0 mg/L;

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb) Acute		
Concentration of Concern (ppb) Chronic	1	
SARs	Aliphatic Amines	
SAR Class	Aliphatic Amines	
TSCA New Chemcial Category	Aliphatic Amines	

Ecotox Factors Comments:

SAT Chair: L Keifer 564-8916
Fate assessor: Ecotox assessor: Health assessor:

Focus Report

New Chemicals Program

PMN Number: **P-13-0817**

Focus Date:	08/28/2013 11:00:00 PM	Report Status:	In Progress
Consolidated Set:	P-13-0816; P-13-0817; P-13-0818; P-13-0819; P-13-0820; P-13-0821		
Focus Chair:	Brian Lee	Contractor:	Olga Svetlitskaya

I. Notice Information

Submitter: [redacted]

CAS Number: [redacted]

Chemical Name: [redacted]

Use: [redacted]

Other Uses:

PV-Max:

Manufacture: X

Import:

II. SAT Results

(1) **Health Rating:** 1-2 **Eco Rating:** 3 **Comments:** ;

Occupational: 0-1 **Non-Occupational:** NR **Environmental:** NR

(1) **PBT:** 1	1	1 Awaiting Human Health Entry Awaiting Human Health Entry Awaiting Human Health Entry	**Comments:**

III. OTHER FACTORS

Categories:

Health Chemical Category:

Ecotox SAR and TSCA New Chemical Category: Aliphatic Amines; Aliphatic Amines

Related Cases/Regulatory History:

Health related Cases:

Ecotox Related Cases:

Regulatory History: [redacted]

CRSS P2Rec: P2Rec-P2 Recognition; SF-Sustainable Futures; XL-Excellence and Leadership; YX-Exposure-Based 5(e)

MSDS/Label Information:

MSDS: Yes Label: No

General Equipment: General ventilation is recommended. Use local exhaust ventilation if necessary to control airborne mist and vapor. // Wear safety glasses with side-shields. // When handling this product, the use of chemical gauntlets is recommended. The choice of work glove depends on work conditions and what chemicals are handled. // Wear chemical resistant apron, chemical splash goggles, impervious gloves and boots. A full slicker suit is recommended if gross exposure is possible.

Respirator: Where concentrations in air may exceed the limits given in this section, the use of air supplied

	breathing apparatus is recommended. In event of emergency or planned entry into unknown concentrations a positive pressure, full-facepiece SCBA should be used.
Health Effects:	Eyes: May cause irritation with prolonged contact. // Skin: May cause irritation with prolonged contact. Toxic in contact with skin. Methanol may be absorbed through the skin and cause central nervous system effects which may result in permanent visual changes including blindness. Skin contact may aggravate an existing dermatitis condition. // Ingestion: Not a likely route of exposure. May cause nausea and vomiting. Can cause central nervous system depression. Toxic if swallowed. Sublethal doses may cause central nervous system effects and may result in permanent visual changes including blindness. // Inhalation: Toxic by inhalation.
TLV/PEL (PMN or raw material):	- Methanol (CASRN 67-56-1) - 60 wt% - TWA - ACGIH - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - ACGIH - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - OSHA Z1 - Methanol (CASRN 67-56-1) - 60 wt% - TWA - OSHA Z1

Exposure Based Information:

Exposure Based Review: [redacted]
Exposure Based Review (Eco): [redacted]
Exposure Based Review (Non Occupatuional):
Exposure Based Review (Health): [redacted]
Exposure Based (Occupational): [redacted]
Exposure Based (Environmental):

IV. Summary of SAT Assessment

Fate:

Fate Summary:

P-13-0816-21 [redacted]
FATE: Estimations for example [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
FATE: Estimations for typical [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 1.77 (E)
log Fish BAF = 1.51 (E)
PMN Substance: [redacted]
[redacted]
POTW removal (%) = 90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = v.strong
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary:

Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for surfactant effects on the lung; irritation to eye, mucous membranes and lung based on surfactant properties of the compound. Also concern for respiratory sensitization based on the [redacted]

Ecotox:

Ecotox Values:

Fish 96-h LC50:	0.504 or *(P)
Daphnid 48-h LC50:	5.3(P)
Green algal 96-h EC50:	0.034(P)
Fish Chronic Value:	0.009(P)
Daphnid ChV:	0.010(P)

Algal ChV: 0.015(P)

Ecotox values comments: Predictions are based on SARs for aliphatic amines with a molecular weight adjustment; SAR chemical class = aliphatic amines; [redacted]; effective concentrations based on 100% active ingredients and mean measured concentrations; DWhardness <150.0 mg/L as CaCO3; and DWTOC <2.0 mg/L;

Ecotox Factors:

Assessment Factor:	10
Concern Concentration: - Acute Value	
Concern Concentration: - Chronic Value	1

V. Summary of Exposures/Releases

Engineering Summary: P-13-0817

Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-13-0817

Exposures/Releases	Release		
Scenario	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]			
[redacted]			
[redacted]			
[redacted]	[redacted]		
Workers			
Exposure Type			

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: PMN Consent Order Decision Date: 08/28/2013
Type of Decision:

Rationale: P-13-0817 will be regulated under the TSCA 5(e) category (aliphatic amines) under the exposure-based authority for ecotoxicity and fate concerns. [redacted] Human health hazard concerns were low-moderate for inhalation exposures. Potential risks to workers were mitigated by negligible vapor exposures. Ecotoxicity hazard concerns were high based on SAR predictions for aliphatic amines. Potential risks to the environment were low due to no exceedances of the COC during the release period. The required ecotoxicity will be the general test strategy in the NCP Chemical Categories document and will be tiered based on the outcome of the fate testing. The required fate testing will be water solubility, Koc and log kow, all in salt water. The submitter may be asked for effluent measurements from [redacted] As of the date these FOCUS notes were finalized EAB has not confirmed the fate testing. The P2REC will not be forwarded based on the high ecotoxicity.

COC: Chronic- 1 ppb, Acute- 9 ppb

Summary of Exposures and Releases

Manu
[redacted]
Dermal: Not required, per SAT

Releases via Incineration: [redacted]

Proc
[redacted]
Dermal: Not required, per SAT

Releases via Incineration: [redacted]

Use
[redacted]
Dermal: Not required, per SAT

Releases to Water: [redacted]

[redacted]

P2 Rec Comments:

Testing:

Prefocus Recommended:

Eco: Chronic Base-Set Tests

Species	EPA Test Guidance	Other parameters
Fish Early Life-Stage	OCSPP 850.1400	Flow-through method, mean measured concentrations, certificate of analysis
Chronic Daphnia	OCSPP 850.1300	Flow-through method, mean measured concentrations, certificate of analysis
Algae	OCSPP 850.4500	Static, mean measured concentrations, protocol review, certificate of analysis

Final Recommended:

Health:

Eco:

Fate:

Other:

SAT Report

PMN Number: **P-13-0817**
SAT Date: **8/23/2013**
Print Date: **6/9/2015**

Related cases: [redacted]

Health related cases:
Ecotox related cases:

Concern levels:

Type of Concern:	**Health**	**Eco**	**Comments**
Level of Concern:	1-2	3	

Persistence	**Bioaccum**	**Toxicity**	**Comments**
1	1	1 Awaiting Human Health Entry Awaiting Human Health Entry Awaiting Human Health Entry	

Exposure Based Review:

Health: No
Ecotox: Yes **Exposure based testing (eco):** Chronic Base-Set Tests

Species	EPA Test Guidance	Other parameters
Fish Early Life-Stage	OCSPP 850.1400	Flow-through method, mean measured concentrations, certificate of analysis
Chronic Daphnia	OCSPP 850.1300	Flow-through method, mean measured concentrations, certificate of analysis
Algae	OCSPP 850.4500	Static, mean measured concentrations, protocol review, certificate of analysis

Routes of exposure:

Health: Inhalation
Ecotox: All releases to water
Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: P-13-0816-21 [redacted]
FATE: Estimations for example [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
FATE: Estimations for typical [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 1.77 (E)
log Fish BAF = 1.51 (E)
PMN Substance: [redacted]
POTW removal (%) = 90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = v.strong
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary: Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for surfactant effects on the lung; irritation to eye, mucous membranes and lung based on surfactant properties of the compound. Also concern for respiratory sensitization based on the [redacted]

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	**96-h**	**LC50**	0.504 or *		
daphnid	**48-h**	**LC50**	5.3		
green algal	**96-h**	**EC50**	0.034		
fish	**_**	**chronic value**	0.009		
daphnid	**_**	**chronic value**	0.010		
algal	**_**	**chronic**	0.015		

		value			
Sewage Sludge	**3-h**	**EC50**	**_**		
Sewage Sludge	**_**	**Chronic Value**	**_**		

Ecotox Values Comments: Predictions are based on SARs for aliphatic amines with a molecular weight adjustment; SAR chemical class = aliphatic amines; [redacted] effective concentrations based on 100% active ingredients and mean measured concentrations; DWhardness <150.0 mg/L as CaCO3; and DWTOC <2.0 mg/L;

Factors	**Values**	**Comments**
Assessment Factor	10	
Concentration of Concern (ppb) Acute		
Concentration of Concern (ppb) Chronic	1	
SARs	Aliphatic Amines	
SAR Class	Aliphatic Amines	
TSCA New Chemcial Category	Aliphatic Amines	

Ecotox Factors Comments:

SAT Chair: L Keifer 564-8916
Fate assessor: Ecotox assessor: Health assessor:

Focus Report

New Chemicals Program

PMN Number: **P-13-0818**

Focus Date:	08/28/2013 11:00:00 PM	Report Status:	In Progress
Consolidated Set:	P-13-0816; P-13-0817; P-13-0818; P-13-0819; P-13-0820; P-13-0821		
Focus Chair:	Brian Lee	Contractor:	Olga Svetlitskaya

I. Notice Information

Submitter: [redacted] CAS Number: [redacted]

Chemical Name: [redacted]

Use: [redacted]

Other Uses:

PV-Max:

Manufacture: X Import:

II. SAT Results

(1) **Health Rating:** 1-2 **Eco Rating:** 3 **Comments:** ;

Occupational: 0-1 **Non-Occupational:** 3 **Environmental:** 3

(1) **PBT:** 1 1 2 **Comments:**

Awaiting Human Health Entry

Awaiting Human Health Entry

Awaiting Human Health Entry

III. OTHER FACTORS

Categories:

Health Chemical Category:

Ecotox SAR and TSCA New Chemical Category: Aliphatic Amines; Aliphatic Amines

Related Cases/Regulatory History:

Health related Cases:

Ecotox Related Cases:

Regulatory History: [redacted]

CRSS P2Rec: P2Rec-P2 Recognition; SF-Sustainable Futures; XL-Excellence and Leadership; YX-Exposure-Based 5(e)

MSDS/Label Information:

MSDS: Yes Label: No

General Equipment: General ventilation is recommended. Use local exhaust ventilation if necessary to control airborne mist and vapor. // Wear safety glasses with side-shields. // When handling this product, the use of chemical gauntlets is recommended. The choice of work glove depends on work conditions and what chemicals are handled. // Wear chemical resistant apron, chemical splash goggles, impervious gloves and boots. A full slicker suit is recommended if gross exposure is possible.

Respirator: Where concentrations in air may exceed the limits given in this section, the use of air supplied

	breathing apparatus is recommended. In event of emergency or planned entry into unknown concentrations a positive pressure, full-facepiece SCBA should be used.
Health Effects:	Eyes: May cause irritation with prolonged contact. // Skin: May cause irritation with prolonged contact. Toxic in contact with skin. Methanol may be absorbed through the skin and cause central nervous system effects which may result in permanent visual changes including blindness. Skin contact may aggravate an existing dermatitis condition. // Ingestion: Not a likely route of exposure. May cause nausea and vomiting. Can cause central nervous system depression. Toxic if swallowed. Sublethal doses may cause central nervous system effects and may result in permanent visual changes including blindness. // Inhalation: Toxic by inhalation.
TLV/PEL (PMN or raw material):	- Methanol (CASRN 67-56-1) - 60 wt% - TWA - ACGIH - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - ACGIH - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - OSHA Z1 - Methanol (CASRN 67-56-1) - 60 wt% - TWA - OSHA Z1

Exposure Based Information:

Exposure Based Review: [redacted]
Exposure Based Review (Eco): [redacted]
Exposure Based Review (Non Occupatuional):
Exposure Based Review (Health): [redacted]
Exposure Based (Occupational): [redacted]
Exposure Based (Environmental):

IV. Summary of SAT Assessment

Fate:

Fate Summary:

P-13-0816-21 [redacted]
FATE: Estimations for example [redacted]
log Kow = [redacted]
log Koc = [redacted]
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FATE: Estimations for [redacted]
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log Fish BCF = 1.77 (E)
log Fish BAF = 1.51 (E)
PMN Substance: [redacted]
[redacted]
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Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = v.strong
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary:

Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for surfactant effects on the lung; irritation to eye, mucous membranes and lung based on surfactant properties of the compound. Also concern for respiratory sensitization and developmental toxicity based on the potential for [redacted] .

Ecotox:

Ecotox Values:

Fish 96-h LC50:	0.504 or *(P)
Daphnid 48-h LC50:	5.3(P)
Green algal 96-h EC50:	0.034(P)
Fish Chronic Value:	0.009(P)
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Ecotox Factors:

Assessment Factor:	10
Concern Concentration: - Acute Value	
Concern Concentration: - Chronic Value	1

V. Summary of Exposures/Releases

Engineering Summary: P-13-0818

Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-13-0818

Exposures/Releases	Release		
Scenario	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]			
[redacted]			
[redacted]			
[redacted]	[redacted]		
Workers			
Exposure Type			

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: PMN Consent Order Decision Date: 08/28/2013
Type of Decision:

Rationale: P-13-0818 will be regulated under the TSCA 5(e) category (aliphatic amines) under the exposure-based authority for ecotoxicity and fate concerns. [redacted]. Human health hazard concerns were low-moderate for inhalation exposures. Potential risks to workers were mitigated by negligible vapor exposures. Ecotoxicity hazard concerns were high based on SAR predictions for aliphatic amines. Potential risks to the environment were low due to no exceedances of the COC during the release period. The required ecotoxicity will be the general test strategy in the NCP Chemical Categories document and will be tiered based on the outcome of the fate testing. The required fate testing will be water solubility, Koc and log kow, all in salt water. The submitter may be asked for effluent measurements from [redacted] As of the date these FOCUS notes were finalized EAB has not confirmed the fate testing. The P2REC will not be forwarded based on the high ecotoxicity.

COC: Chronic- 1 ppb, Acute- 9 ppb

Summary of Exposures and Releases

Manu
[redacted]
Dermal: Not required, per SAT

Releases via Incineration: [redacted]

[redacted]
Dermal: Not required, per SAT

Releases via Incineration: [redacted]

Fate Releases to Air:
Stack Air: LADD: 1.50E-03 mg/kg/day, ADR: 3.40E-01 mg/kg/day

Use
[redacted]
Dermal: Not required, per SAT

Releases to Water: [redacted]

[redacted]

[redacted]

Fate Releases to Air:
Stack Air: LADD: 1.62E-03 mg/kg/day

P2 Rec Comments:

Testing:

Prefocus Recommended:

Eco: Chronic Base-Set Tests

Species	EPA Test Guidance	Other parameters
Fish Early Life-Stage	OCSPP 850.1400	Flow-through method, mean measured concentrations, certificate of analysis
Chronic Daphnia	OCSPP 850.1300	Flow-through method, mean measured concentrations, certificate of analysis
Algae	OCSPP 850.4500	Static, mean measured concentrations, protocol review, certificate of analysis

Final Recommended:

Health:
Eco:
Fate:
Other:

SAT Report

PMN Number: **P-13-0818**
SAT Date: **8/23/2013**
Print Date: **6/9/2015**

Related cases: [redacted]

Health related cases:
Ecotox related cases:

Concern levels:

Type of Concern:	**Health**	**Eco**	**Comments**
Level of Concern:	1-2	3	

Persistence	**Bioaccum**	**Toxicity**	**Comments**
1	1	2	
		Awaiting Human Health Entry	
		Awaiting Human Health Entry	
		Awaiting Human Health Entry	

Exposure Based Review:

Health: No
Ecotox: Yes **Exposure based testing (eco):** Chronic Base-Set Tests

Species	EPA Test Guidance	Other parameters
Fish Early Life-Stage	OCSPP 850.1400	Flow-through method, mean measured concentrations, certificate of analysis
Chronic Daphnia	OCSPP 850.1300	Flow-through method, mean measured concentrations, certificate of analysis
Algae	OCSPP 850.4500	Static, mean measured concentrations, protocol review, certificate of analysis

Routes of exposure:

Health: Inhalation
Ecotox: All releases to water
Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: P-13-0816-21 [redacted]
FATE: Estimations for example [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
FATE: Estimations for typical [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 1.77 (E)
log Fish BAF = 1.51 (E)
PMN Substance: [redacted]
[redacted]
POTW removal (%) = 90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = v.strong
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary: Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for surfactant effects on the lung; irritation to eye, mucous membranes and lung based on surfactant properties of the compound. Also concern for respiratory sensitization and developmental toxicity based on the potential for [redacted]

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	**96-h**	**LC50**	0.504 or *		
daphnid	**48-h**	**LC50**	5.3		
green algal	**96-h**	**EC50**	0.034		
fish	**_**	**chronic value**	0.009		
daphnid	**_**	**chronic value**	0.010		

algal	**_**	**chronic value**	0.015		
Sewage Sludge	**3-h**	**EC50**	**_**		
Sewage Sludge	**_**	**Chronic Value**	**_**		

Ecotox Values Comments: Predictions are based on SARs for aliphatic amines with a molecular weight adjustment; SAR chemical class = aliphatic amines; [redacted]; effective concentrations based on 100% active ingredients and mean measured concentrations; DWhardness <150.0 mg/L as CaCO3; and DWTOC <2.0 mg/L;

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb) Acute		
Concentration of Concern (ppb) Chronic	1	
SARs	Aliphatic Amines	
SAR Class	Aliphatic Amines	
TSCA New Chemcial Category	Aliphatic Amines	

Ecotox Factors Comments:

SAT Chair: L Keifer 564-8916
Fate assessor: Ecotox assessor: Health assessor:

Briefing Paper

Case Number: **P-13-0819**

Part I: Background Data

Program Manager: Jeff Bauer
Technical Integrator:
Review Team:
Meeting Date:
Day In Process: 50
Day 90: 11/04/2013

A. CBI Claims:
B. Submitter:
C. Chemical Identity:
D. Chemical Class:
Ecotox: Aliphatic Amines ; Aliphatic Amines

E. Structure:

F. Physical/Chemical properties:
VP:
C
s-H2O:
MW:
Phys State:
Neat:
Manufacturing:
Process/Form:
End Use:

G. Volume:
H. Use:

I. Test Data Submitted:
J. MSDS:
MSDS: Yes
Label: No
General equipment: General ventilation is recommended. Use local exhaust ventilation if necessary to control airborne mist and vapor. // Wear safety glasses with side-shields. // When handling this product, the use of chemical gauntlets is recommended. The choice of work glove depends on work conditions and what chemicals are handled. // Wear chemical resistant apron, chemical splash goggles, impervious gloves and boots. A full slicker suit is recommended if gross exposure is possible.
Respirator: Where concentrations in air may exceed the limits given in this section, the use of air supplied breathing apparatus is recommended. In event of emergency or planned entry into unknown concentrations a positive pressure, full-facepiece SCBA should be used.
Health Effects: Eyes: May cause irritation with prolonged contact. // Skin: May cause irritation with prolonged contact. Toxic in contact with skin. Methanol may be absorbed through the skin and cause central nervous system effects which may result in permanent visual changes including

blindness. Skin contact may aggravate an existing dermatitis condition. // Ingestion: Not a likely route of exposure. May cause nausea and vomiting. Can cause central nervous system depression. Toxic if swallowed. Sublethal doses may cause central nervous system effects and may result in permanent visual changes including blindness. // Inhalation: Toxic by inhalation.

K. SAT Ratings:
Human Health: 1-2 ; Environment: 3 ;

L. Focus Results: P-13-0819 will be regulated under the TSCA 5(e) category (aliphatic amines) under the exposure-based authority for ecotoxicity and fate concerns. [redacted] Human health hazard concerns were low-moderate for inhalation exposures. Potential risks to workers were mitigated by negligible vapor exposures. Ecotoxicity hazard concerns were high based on SAR predictions for aliphatic amines. Potential risks to the environment were low due to no exceedances of the COC during the release period. The required ecotoxicity will be the general test strategy in the NCP Chemical Categories document and will be tiered based on the outcome of the fate testing. The required fate testing will be water solubility, Koc and log kow, all in salt water. The submitter may be asked for effluent measurements from [redacted]. As of the date these FOCUS notes were finalized EAB has not confirmed the fate testing. The P2REC will not be forwarded based on the high ecotoxicity.

COC: Chronic- 1 ppb, Acute- 9 ppb

Summary of Exposures and Releases

Manu
[redacted]
Dermal: Not required, per SAT

Releases via Incineration: [redacted]

Proc
[redacted]
Dermal: Not required, per SAT

Releases via Incineration: [redacted]

Use
[redacted]
Dermal: Not required, per SAT

Releases to Water: [redacted]

[redacted]

Part II: New Information

Part III: Recommendation and Rationale

P13-810 thru 815 and P13-816 thru 821, Two sets of consolidated cases. The Focus decission was to regulate under an exposure based order, However no triggers were met and the Focus decission will be changed to a Non

5(e) SNUR for a water trigger of 1 ppb. The chronic COC for all 12 cases is 1 ppb but the acute COC varies slightly

The Program Manager recommends the PMN be dropped from further review with a Non 5(e) SNUR with a water trigger of 1 ppb. The testing in the SNUR will be:

Tier A: Water solubility test, log Kow, and log Koc in representative salt water conditions with the PMN

Based on EPA's review of the results of these studies, EPA will either choose:

Tier B1: OPPTS 850.1075 (Marine acute fish toxicity test), OPPTS 850.1035 (Mysid acute toxicity test), and OCSPP 850.4500 (Marine algal toxicity test) OR

Tier B2: OPPTS 850.1740 (Whole sediment acute toxicity invertebrates, marine)

Part IV: Risk Summary

A. Health Effects:

Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for surfactant effects on the lung; irritation to eye, mucous membranes and lung based on surfactant properties of the compound.

B. Environmental Effects:

Ecotox: predicted (P) and measured (M) toxicity value is mg/L (ppm) are:

Fish 96-h LC50:	0.504 or *(P)
Daphnid 48-h LC50:	5.3(P)
Green algal 96-h EC50:	0.034(P)
Fish Chronic Value:	0.009(P)
Daphnid ChV:	0.010(P)
Algal ChV:	0.015(P)

C. Environmental Releases and Exposures:

D. Risk Estimates:

Part V: Exposure Criteria Met

Exposure Based Review (Chemistry): [redacted]

Exposure Based Review (Ecotox):

Exposure Based Review (Non-Occupational)

Exposure Based Review (Health): [redacted]

Exposure Based Review (Occupational):

Exposure Based Review (Environmental):

Exposure Parameter	Exposure-Based	Persistent/Bioaccum	Exposure Value

Surface DW:	◯ Yes ◯ No	◯ Yes ◯ No	
Fish Ingestion:	◯ Yes ◯ No	◯ Yes ◯ No	
Ground DW:	◯ Yes ◯ No	◯ Yes ◯ No	
Inhalation:	◯ Yes ◯ No	◯ Yes ◯ No	
Water Releases:	◯ Yes ◯ No	◯ Yes ◯ No	
Total Releases:	◯ Yes ◯ No	◯ Yes ◯ No	
Consumer Exposure:	◯ Yes ◯ No	◯ Yes ◯ No	

Part VI: Tests

Final Testing Recommendation

Health:
Eco:
Fate:
Other:

Comments:

Part VII: Other Factors

A. Substitutes:

B. Benefits:

C. Other Uses: [redacted].

D. Other:

Part VIII: Regulatory History

[redacted]

Comments:

Last Updated by

Document Created by Jeff Bauer **on** 09/25/2013

Focus Report

New Chemicals Program

PMN Number: **P-13-0819**

Focus Date:	08/28/2013 11:00:00 PM	Report Status:	In Progress
Consolidated Set:	P-13-0816; P-13-0817; P-13-0818; P-13-0819; P-13-0820; P-13-0821		
Focus Chair:	Brian Lee	Contractor:	Olga Svetlitskaya

I. Notice Information

Submitter:

CAS Number:

Chemical Name:

Use:

Other Uses:

PV-Max:

Manufacture: X

Import:

II. SAT Results

(1) **Health Rating:** 1-2 **Eco Rating:** 3 **Comments:** ;

Occupational: 0-1 **Non-Occupational:** NR **Environmental:** NR

(1) **PBT:** 1 1 1 **Comments:**

Awaiting Human Health Entry

Awaiting Human Health Entry

Awaiting Human Health Entry

III. OTHER FACTORS

Categories:

Health Chemical Category:

Ecotox SAR and TSCA New Chemical Category: Aliphatic Amines; Aliphatic Amines

Related Cases/Regulatory History:

Health related Cases:

Ecotox Related Cases:

Regulatory History:

CRSS P2Rec: P2Rec-P2 Recognition; SF-Sustainable Futures; XL-Excellence and Leadership; YX-Exposure-Based 5(e)

MSDS/Label Information:

MSDS: Yes Label: No

General Equipment: General ventilation is recommended. Use local exhaust ventilation if necessary to control airborne mist and vapor. // Wear safety glasses with side-shields. // When handling this product, the use of chemical gauntlets is recommended. The choice of work glove depends on work conditions and what chemicals are handled. // Wear chemical resistant apron, chemical splash goggles, impervious gloves and boots. A full slicker suit is recommended if gross exposure is possible.

Respirator: Where concentrations in air may exceed the limits given in this section, the use of air supplied

	breathing apparatus is recommended. In event of emergency or planned entry into unknown concentrations a positive pressure, full-facepiece SCBA should be used.
Health Effects:	Eyes: May cause irritation with prolonged contact. // Skin: May cause irritation with prolonged contact. Toxic in contact with skin. Methanol may be absorbed through the skin and cause central nervous system effects which may result in permanent visual changes including blindness. Skin contact may aggravate an existing dermatitis condition. // Ingestion: Not a likely route of exposure. May cause nausea and vomiting. Can cause central nervous system depression. Toxic if swallowed. Sublethal doses may cause central nervous system effects and may result in permanent visual changes including blindness. // Inhalation: Toxic by inhalation.
TLV/PEL (PMN or raw material):	- Methanol (CASRN 67-56-1) - 60 wt% - TWA - ACGIH - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - ACGIH - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - OSHA Z1 - Methanol (CASRN 67-56-1) - 60 wt% - TWA - OSHA Z1

Exposure Based Information:

Exposure Based Review: [redacted]	Exposure Based Review (Health): [redacted]
Exposure Based Review (Eco): [redacted]	Exposure Based (Occupational): [redacted]
Exposure Based Review (Non Occupatuional):	Exposure Based (Environmental):

IV. Summary of SAT Assessment

Fate:

Fate Summary:

P-13-0816-21 [redacted]
FATE: Estimations for example [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
FATE: Estimations for typical [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 1.77 (E)
log Fish BAF = 1.51 (E)
PMN Substance: [redacted]
[redacted] (%) = 90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = v.strong
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary: Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for surfactant effects on the lung; irritation to eye, mucous membranes and lung based on surfactant properties of the compound.

Ecotox:

Ecotox Values:

Fish 96-h LC50:	0.504 or *(P)
Daphnid 48-h LC50:	5.3(P)
Green algal 96-h EC50:	0.034(P)
Fish Chronic Value:	0.009(P)
Daphnid ChV:	0.010(P)
Algal ChV:	0.015(P)

Ecotox values comments: Predictions are based on SARs for aliphatic amines with a molecular weight adjustment; SAR chemical class = aliphatic amines; [redacted] effective concentrations based on 100% active ingredients and mean measured concentrations; DWhardness <150.0 mg/L as CaCO3; and DWTOC <2.0 mg/L;

Ecotox Factors:

Assessment Factor:	10
Concern Concentration: - Acute Value	
Concern Concentration: - Chronic Value	1

V. Summary of Exposures/Releases

Engineering Summary: P-13-0819

Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-13-0819

Exposures/Releases	Release		
Scenario	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]			
[redacted]			
[redacted]			
[redacted]	[redacted]		
Workers			
Exposure Type			

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: PMN Consent Order Decision Date: 08/28/2013
Type of Decision:

Rationale: P-13-0819 will be regulated under the TSCA 5(e) category (aliphatic amines) under the exposure-based authority for ecotoxicity and fate concerns. [redacted] Human health hazard concerns were low-moderate for inhalation exposures. Potential risks to workers were mitigated by negligible vapor exposures. Ecotoxicity hazard concerns were high based on SAR predictions for aliphatic amines. Potential risks to the environment were low due to no exceedances of the COC during the release period. The required ecotoxicity will be the general test strategy in the NCP Chemical Categories document and will be tiered based on the outcome of the fate testing. The required fate testing will be water solubility, Koc and log kow, all in salt water. The submitter may be asked for effluent measurements from [redacted] As of the date these FOCUS notes were finalized EAB has not confirmed the fate testing. The P2REC will not be forwarded based on the high ecotoxicity.

COC: Chronic- 1 ppb, Acute- 9 ppb

Summary of Exposures and Releases

Manu
[redacted]
Dermal: Not required, per SAT

Releases via Incineration: [redacted]

Proc
[redacted]
Dermal: Not required, per SAT

Releases via Incineration: [redacted]

Use
[redacted]
Dermal: Not required, per SAT

Releases to Water: [redacted]

[redacted]

P2 Rec Comments:

Testing:

Prefocus Recommended:

Eco: Chronic Base-Set Tests

Species	EPA Test Guidance	Other parameters
Fish Early Life-Stage	OCSPP 850.1400	Flow-through method, mean measured concentrations, certificate of analysis
Chronic Daphnia	OCSPP 850.1300	Flow-through method, mean measured concentrations, certificate of analysis
Algae	OCSPP 850.4500	Static, mean measured concentrations, protocol review, certificate of analysis

Final Recommended:

Health:

Eco:

Fate:

Other:

SAT Report

PMN Number: **P-13-0819**
SAT Date: **8/23/2013**
Print Date: **6/9/2015**

Related cases: [redacted]

Health related cases:
Ecotox related cases:

Concern levels:

Type of Concern:	**Health**	**Eco**	**Comments**
Level of Concern:	1-2	3	

Persistence	**Bioaccum**	**Toxicity**	**Comments**
1	1	1	
		Awaiting Human Health Entry	
		Awaiting Human Health Entry	
		Awaiting Human Health Entry	

Exposure Based Review:

Health: No
Ecotox: Yes **Exposure based testing (eco):** Chronic Base-Set Tests

Species	EPA Test Guidance	Other parameters
Fish Early Life-Stage	OCSPP 850.1400	Flow-through method, mean measured concentrations, certificate of analysis
Chronic Daphnia	OCSPP 850.1300	Flow-through method, mean measured concentrations, certificate of analysis
Algae	OCSPP 850.4500	Static, mean measured concentrations, protocol review, certificate of analysis

Routes of exposure:

Health: Inhalation
Ecotox: All releases to water
Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: P-13-0816-21 [redacted]
FATE: Estimations for example [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
FATE: Estimations for typical [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 1.77 (E)
log Fish BAF = 1.51 (E)
PMN Substance: [redacted]
[redacted]
POTW removal (%) = 90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = v.strong
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary: Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for surfactant effects on the lung; irritation to eye, mucous membranes and lung based on surfactant properties of the compound.

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	**96-h**	**LC50**	0.504 or *		
daphnid	**48-h**	**LC50**	5.3		
green algal	**96-h**	**EC50**	0.034		
fish	**_**	**chronic value**	0.009		
daphnid	**_**	**chronic value**	0.010		
algal	**_**	**chronic value**	0.015		

Sewage Sludge	**3-h**	**EC50**	**_**		
Sewage Sludge	**_**	**Chronic Value**	**_**		

Ecotox Values Comments: Predictions are based on SARs for aliphatic amines with a molecular weight adjustment; SAR chemical class = aliphatic amines; [redacted]; effective concentrations based on 100% active ingredients and mean measured concentrations; DWhardness <150.0 mg/L as CaCO3; and DWTOC <2.0 mg/L;

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb) Acute		
Concentration of Concern (ppb) Chronic	1	
SARs	Aliphatic Amines	
SAR Class	Aliphatic Amines	
TSCA New Chemcial Category	Aliphatic Amines	

Ecotox Factors Comments:

SAT Chair: L Keifer 564-8916
Fate assessor: Ecotox assessor: Health assessor:

Focus Report

New Chemicals Program

PMN Number: **P-13-0820**

Focus Date:	08/28/2013 11:00:00 PM	Report Status:	In Progress
Consolidated Set:	P-13-0816; P-13-0817; P-13-0818; P-13-0819; P-13-0820; P-13-0821		
Focus Chair:	Brian Lee	Contractor:	Olga Svetlitskaya

I. Notice Information

Submitter: [redacted] CAS Number: [redacted]

Chemical Name: [redacted]

Use: [redacted]

Other Uses:

PV-Max:

Manufacture: X Import:

II. SAT Results

(1) **Health Rating:** 1-2 **Eco Rating:** 3 **Comments:** ;

Occupational: 0-1 **Non-Occupational:** NR **Environmental:** NR

(1) **PBT:** 1 1 1 **Comments:**

Awaiting Human Health Entry

Awaiting Human Health Entry

Awaiting Human Health Entry

III. OTHER FACTORS

Categories:

Health Chemical Category:

Ecotox SAR and TSCA New Chemical Category: Aliphatic Amines; Aliphatic Amines

Related Cases/Regulatory History:

Health related Cases:

Ecotox Related Cases:

Regulatory History: [redacted]

CRSS P2Rec: P2Rec-P2 Recognition; SF-Sustainable Futures; XL-Excellence and Leadership; YX-Exposure-Based 5(e)

MSDS/Label Information:

MSDS: Yes Label: No

General Equipment: General ventilation is recommended. Use local exhaust ventilation if necessary to control airborne mist and vapor. // Wear safety glasses with side-shields. // When handling this product, the use of chemical gauntlets is recommended. The choice of work glove depends on work conditions and what chemicals are handled. // Wear chemical resistant apron, chemical splash goggles, impervious gloves and boots. A full slicker suit is recommended if gross exposure is possible.

Respirator: Where concentrations in air may exceed the limits given in this section, the use of air supplied

	breathing apparatus is recommended. In event of emergency or planned entry into unknown concentrations a positive pressure, full-facepiece SCBA should be used.
Health Effects:	Eyes: May cause irritation with prolonged contact. // Skin: May cause irritation with prolonged contact. Toxic in contact with skin. Methanol may be absorbed through the skin and cause central nervous system effects which may result in permanent visual changes including blindness. Skin contact may aggravate an existing dermatitis condition. // Ingestion: Not a likely route of exposure. May cause nausea and vomiting. Can cause central nervous system depression. Toxic if swallowed. Sublethal doses may cause central nervous system effects and may result in permanent visual changes including blindness. // Inhalation: Toxic by inhalation.
TLV/PEL (PMN or raw material):	- Methanol (CASRN 67-56-1) - 60 wt% - TWA - ACGIH - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - ACGIH - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - STEL - NIOSH REL - Skin - Methanol (CASRN 67-56-1) - 60 wt% - TWA - OSHA Z1 - Methanol (CASRN 67-56-1) - 60 wt% - TWA - OSHA Z1

Exposure Based Information:

Exposure Based Review: [redacted]
Exposure Based Review (Eco): [redacted]
Exposure Based Review (Non Occupatuional):
Exposure Based Review (Health): [redacted]
Exposure Based (Occupational): [redacted]
Exposure Based (Environmental):

IV. Summary of SAT Assessment

Fate:

Fate Summary:

P-13-0816-21 [redacted]
FATE: Estimations for example [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
FATE: Estimations for typical [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 1.77 (E)
log Fish BAF = 1.51 (E)
PMN Substance: [redacted]
[redacted]
POTW removal (%) = 90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = v.strong
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary:

Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for surfactant effects on the lung; irritation to eye, mucous membranes and lung based on surfactant properties of the compound. Also concern for respiratory sensitization based on [redacted]

Ecotox:

Ecotox Values:

Fish 96-h LC50:	0.504 or *(P)
Daphnid 48-h LC50:	5.3(P)
Green algal 96-h EC50:	0.034(P)
Fish Chronic Value:	0.009(P)
Daphnid ChV:	0.010(P)

Algal ChV:	0.015(P)

Ecotox values comments: Predictions are based on SARs for aliphatic amines with a molecular weight adjustment; SAR chemical class = aliphatic amines; [redacted] effective concentrations based on 100% active ingredients and mean measured concentrations; DWhardness <150.0 mg/L as CaCO3; and DWTOC <2.0 mg/L;

Ecotox Factors:

Assessment Factor:	10
Concern Concentration: - Acute Value	
Concern Concentration: - Chronic Value	1

V. Summary of Exposures/Releases

Engineering Summary: P-13-0820

Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-13-0820

Exposures/Releases	Release		
Scenario	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]			
[redacted]			
[redacted]			
[redacted]	[redacted]		
Workers			
Exposure Type			

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: PMN Consent Order Decision Date: 08/28/2013
Type of Decision:

Rationale: P-13-0820 will be regulated under the TSCA 5(e) category (aliphatic amines) under the exposure-based authority for ecotoxicity and fate concerns. [redacted] Human health hazard concerns were low-moderate for inhalation exposures. Potential risks to workers were mitigated by negligible vapor exposures. Ecotoxicity hazard concerns were high based on SAR predictions for aliphatic amines. Potential risks to the environment were low due to no exceedances of the COC during the release period. The required ecotoxicity will be the general test strategy in the NCP Chemical Categories document and will be tiered based on the outcome of the fate testing. The required fate testing will be water solubility, Koc and log kow, all in salt water. The submitter may be asked for effluent measurements [redacted] As of the date these FOCUS notes were finalized EAB has not confirmed the fate testing. The P2REC will not be forwarded based on the high ecotoxicity.

COC: Chronic- 1 ppb, Acute- 9 ppb

Summary of Exposures and Releases

Manu
[redacted]
Dermal: Not required, per SAT

Releases via Incineration: [redacted]

Proc
[redacted]
Dermal: Not required, per SAT

Releases via Incineration: [redacted]

Use
[redacted]
Dermal: Not required, per SAT

Releases to Water: [redacted]

[redacted]

P2 Rec Comments:

Testing:

Prefocus Recommended:

Eco: Chronic Base-Set Tests

Species	EPA Test Guidance	Other parameters
Fish Early Life-Stage	OCSPP 850.1400	Flow-through method, mean measured concentrations, certificate of analysis
Chronic Daphnia	OCSPP 850.1300	Flow-through method, mean measured concentrations, certificate of analysis
Algae	OCSPP 850.4500	Static, mean measured concentrations, protocol review, certificate of analysis

Final Recommended:

Health:

Eco:

Fate:

Other:

SAT Report

PMN Number: **P-13-0820**
SAT Date: **8/23/2013**
Print Date: **6/9/2015**

Related cases: [redacted]

Health related cases:
Ecotox related cases:

Concern levels:

Type of Concern:	**Health**	**Eco**	**Comments**
Level of Concern:	1-2	3	

Persistence	**Bioaccum**	**Toxicity**	**Comments**
1	1	1	
		Awaiting Human Health Entry	
		Awaiting Human Health Entry	
		Awaiting Human Health Entry	

Exposure Based Review:

Health: No
Ecotox: Yes **Exposure based testing (eco):** Chronic Base-Set Tests

Species	EPA Test Guidance	Other parameters
Fish Early Life-Stage	OCSPP 850.1400	Flow-through method, mean measured concentrations, certificate of analysis
Chronic Daphnia	OCSPP 850.1300	Flow-through method, mean measured concentrations, certificate of analysis
Algae	OCSPP 850.4500	Static, mean measured concentrations, protocol review, certificate of analysis

Routes of exposure:

Health: Inhalation
Ecotox: All releases to water
Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: P-13-0816-21 [redacted]
FATE: Estimations for example [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
FATE: Estimations for typical [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 1.77 (E)
log Fish BAF = 1.51 (E)
PMN Substance: [redacted]
POTW removal (%) = 90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = v.strong
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary: Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for surfactant effects on the lung; irritation to eye, mucous membranes and lung based on surfactant properties of the compound. Also concern for respiratory sensitization based on [redacted]

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	**96-h**	**LC50**	0.504 or *		
daphnid	**48-h**	**LC50**	5.3		
green algal	**96-h**	**EC50**	0.034		
fish	**_**	**chronic value**	0.009		
daphnid	**_**	**chronic value**	0.010		
algal	**_**	**chronic**	0.015		

		value			
Sewage Sludge	**3-h**	**EC50**	**_**		
Sewage Sludge	**_**	**Chronic Value**	**_**		

Ecotox Values Comments: Predictions are based on SARs for aliphatic amines with a molecular weight adjustment; SAR chemical class = aliphatic amines; [redacted] effective concentrations based on 100% active ingredients and mean measured concentrations; DWhardness <150.0 mg/L as CaCO3; and DWTOC <2.0 mg/L;

Factors	**Values**	**Comments**
Assessment Factor	10	
Concentration of Concern (ppb) Acute		
Concentration of Concern (ppb) Chronic	1	
SARs	Aliphatic Amines	
SAR Class	Aliphatic Amines	
TSCA New Chemcial Category	Aliphatic Amines	

Ecotox Factors Comments:

SAT Chair: L Keifer 564-8916
Fate assessor: Ecotox assessor: Health assessor: